DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Richard Wolf Medical Instruments Corporation
Robert L. Casarsa
Quality Assurance Manager
353 Corporate Woods Parkway
Vernon Hills, IL 60061

JUL 27 2015

Re: K023659
Trade/Device Name: 1 – CCD Endocam 5520 System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FET
Dated (Date on orig SE ltr): October 31, 2002
Received (Date on orig SE ltr): October 31, 2002

Dear Mr. Casarsa,

This letter corrects our substantially equivalent letter of January 29, 2003.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

5.0 INDICATIONS FOR USE

510(k) Number (if known): — K023659

Device Name: 1-CCD Endocam 5520 System

Intended use: The 1 CCD ENDOCAM 5520 is designed for video endoscopy and video microscopy and can be used for diagnostic and therapeutic applications.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023659

Prescription Use ✓ OR Over-The Counter _____
Per 21 CFR 801.109

(Optional Format 1-2-96)

JAN 2 9 2003

RICHARD WOLF
Medical Instruments Corporation

K023659

353 Corporate Woods Parkway
Vernon Hills, IL 60061
Phone: 847-913-1113
Customer Service: 800-323-WOLF
www.richard-wolf.com

13.0 510(k) Summary of Safety and Effectiveness

Submitter:			Date of Preparation: **October 31, 2002**
Company / Institution name: **RICHARD WOLF MEDICAL INSTRUMENTS CORP.**			FDA establishment registration number: 14 184 79
Division name (if applicable): N.A.			Phone number (include area code): (847) 913 1113
Street address: 353 Corporate Woods Parkway			FAX number (include area code): (847) 913 0924
City: Vernon Hills	State/Province: Illinois	Country: USA	ZIP / Postal Code: IL 60061
Contact name: Mr. Robert L. Casarsa			
Contact title: Quality Assurance Manager			
Product Information:			
Trade name: 1 CCD Endocam		Model number: 5520.xxx; 85520.xxx, 8934.551 85264.xxx	
Common name: Endoscopic Video Camera System		Classification name: Endoscope and/or Accessories	

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K982965	1 1-CCD endocam 5502 and 3-CCD endocam 5507 with CF camera heads	1 Richard Wolf
2 K983279	2 1-CCD multi-endocam 5502 with electronic CCD endoscope	2 Richard Wolf
3 K950502	3 1-CCD endocam 5501	3 Richard Wolf
4 K002328	4 SIOS-Interface for 3CCD Endocam 5507.752	4 Richard Wolf
5 K964173	5 C-mount objective lenses, autoclavable	5 Richard Wolf

1.0 Description

The 1-CCD Endocam 5520 device is a further development of previous 1-CCD Endocams with additional features. Various Camera Heads with and without integrated lenses and CCD endoscopes are available.

2.0 Intended Use

The 1 CCD ENDOCAM 5520 is designed for video endoscopy and video microscopy and can be used for diagnostic and therapeutic applications. The 1 CCD ENDOCAM 5520 is designed for connection to various camera heads and CCD endoscopes.

In conjunction with video recorders / video printers and other video equipment it can be used for recording and storing video images.

The camera heads and the CCD endoscope are used in connection with the 1 CCD ENDOCAM 5520 controller for diagnostic and therapeutic applications. Free rotation and self-alignment of the urological camera heads results in an endoscope image, which is always correctly positioned.

3.0 Technological Characteristics

The 1-CCD Endocam 5520 System has additional features such as digital zoom, mirror imaging, anti-Moiré, and interfaces for digital video output (IEEE 1394), RIWONET control, keyboard and remote control.

4.0 Substantial Equivalence

The submitted devices pose the same type of questions about safety or effectiveness as the compared devices and the new technological characteristics have not diminished safety or effectiveness. The submitted devices are substantially equivalent to existing 510(k)-devices sold by Richard Wolf.

5.0 Performance Data

The Endocam systems 5520 was tested for conformity with the specified standards UL2601-1, IEC601-2-18, CSA22.2No.601.1.

6.0 Clinical Tests

No clinical tests performed.

7.0 Conclusions Drawn

These devices are designed and tested to guarantee the safety and effectiveness, when used according to the instructions manual.

By: Robert L. Casarsa Date: Oct. 30, 2002

Robert L. Casarsa
Quality Assurance Manager